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TITLE: Responsiveness of a Neuromuscular Recovery Scale for Spinal Cord Injury: Inpatient and Outpatient Rehabilitation

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14. ABSTRACT

This multi-centered study (8 performance sites) assesses the responsiveness of the Neuromuscular Recovery Scale (NRS) for people with spinal cord injury. The NRS evaluates true recovery of pre-injury movement, rather than compensatory progress, during inpatient and outpatient rehabilitation for spinal cord injury. At the time of this report, approval has been received for the coordinating site, the University of Florida and for one clinical performance site, the Ohio State University. Enrollment and data collection is underway as sites are approved. Three other clinical performance sites are under review by the HRPO and will commence with data collection upon approval. Web-site construction is under development through streaming web services at Ohio State University (OSU) to provide an introduction to the NRS via video and an instructional guide. Training of the James A. Haley VA Medical Center (Tampa VA) physical therapists in use of the NRS was conducted and completed at OSU and electronic data transfer approvals are underway by the VA.

15. SUBJECT TERMS
Neuromuscular Recovery Scale (NRS), spinal cord injury, multicenter study

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Introduction

The purpose of this study is to assess the responsiveness of the phase system (Neuromuscular Recovery Scale, NRS) in measuring recovery from SCI over time and across therapy settings. This scale uniquely detects return of normal function over time after SCI. Compensation for weakened or paralyzed muscles by stronger muscles, substitutions, or devices do not contribute to the score. Preliminary data indicate the current utility of the NRS to distinctly classify people with SCI based on performance of normal, pre-morbid movement function. Our intent is that the NRS will serve as a clinically-relevant SCI outcome measure for use in rehabilitation clinics, cohort studies, and randomized clinical trials.

Hypothesis

We hypothesize that individuals post-SCI undergoing physical rehabilitation will demonstrate significant change in Neuromuscular Recovery Scale scores from initial to discharge evaluations during the period of a) in-patient rehabilitation and usual care and b) outpatient rehabilitation (chronic SCI) receiving an intense, activity-based therapy.

Specific Aims

Aim 1: Assess the responsiveness of the Neuromuscular Recovery Scale for evaluating recovery from SCI over the period of 1) in-patient rehabilitation (sub-acute SCI) receiving usual care and 2) outpatient rehabilitation (chronic SCI) while receiving an intense, activity-based therapy.

A) Ninety-four patients, AIS A, B, C & D undergoing *usual* care rehabilitation in an inpatient setting during the sub-acute period post-SCI will be enrolled for completion of initial and discharge Phase System evaluations. We anticipate attrition will result in a study population of 72 subjects with initial and discharge evaluations.

B) Seventy-two NeuroRecovery Network (NRN) patients, chronic AIS A-D undergoing the standardized locomotor training program in an out-patient rehabilitation program will undergo initial and discharge evaluations. Only persons included in the NRN database having completed both initial and discharge evaluations will be included in our dataset.

Relevance

The results of this study will establish the ability of the NRS to detect rehabilitation-induced changes in recovery of function after acute or chronic SCI. By being able to classify initial functional deficits with the NRS, we will be able to better tailor interventions for each individual with SCI. By including VA and military personnel in the study, incorporation of the NRS in the care and treatment of soldiers or veterans with SCI will be immediate. Furthermore, web documents will support training of other military rehabilitation centers.

Body

As outlined in our SOW, we dedicated considerable time attaining human subject approval, setting up procedures and attaining electronic data transfer approval for the Tampa VA, training the James A Haley VA Medical Hospital (Tampa VA) physical therapists and enrolling subjects. As we are leveraging the standard clinical practice of the NeuroRecovery Network in routinely evaluating out-patients with the NRS at initial evaluation and discharge, we additionally incorporated three upper extremity items consistent with the NRN. These items were added to the NRS in May, 2011 and should assist in better gauging responsiveness as now the legs, trunk, and arms are all encompassed in the assessment. The approved IRB includes all of these items.

Task 1. Prepare and standardize all sites (NRN and Tampa VA) for data collection (Months 0-10)

1a. Planning meetings held among partnering investigators, statistician, and Systemax Corp.
- COMPLETED

1b. Planning meeting held for NRN sites and Tampa VA with a) site PI and b) site Supervisors; ongoing monthly meetings scheduled
- COMPLETED

1c. Prepare and submit IRB materials to each institution. Revise, as requested by IRB for approval.
- UNDERWAY

Milestone #1 Human Use Approvals – 2 centers have been approved, 3 centers have obtained institutional approval and are under review by HRPO, 1 center has materials under institutional IRB review, 2 centers have not submitted IRB documents at this time. Tampa VA IRB documents are in preparation.

1d. Tampa VA study staff visits NRN-OSU clinical site for Phase System/NRS training. On-site competency skills checklist completed and passed.
- COMPLETED

1e. After practice with 3-5 patients, Tampa VA completes and passes competency skills checklist for conducting NRS at Tampa VA site via submission of Phase System/NRS evaluation recording.
- PENDING IRB APPROVAL

1f. NRN sites and Tampa VA site establishes procedures for patient/subject referral and data collection with in-patient rehabilitation SCI program
- UNDERWAY for those centers with full approval

Milestone #2 All sites readied for data collection with Phase System instrument and in-patient SCI population

1g. Establish and modify database
- COMPLETED

1h. Tampa VA site added to 7 NRN sites as a research site for data entry to database

- DATABASE COMPLETED FOR VA SITE pending approval for electronic data transfer by VA

1i. Develop website for dissemination of instrument at introductory level including on-line video demonstrations. (preparation for dissemination – Year 2)

- UNDERWAY-video production and web site in development at OSU

Milestone #3. Active database for all partnering institutions and clinical sites

- COMPLETED

Task 2 Determine responsiveness of the Phase System (9-20 months)

2a. Identify subjects from NRN outpatient Locomotor Training programs

- UNDERWAY at approved IRB sites

2b. Collect NRS evaluation data at initial and discharge

- UNDERWAY at approved IRB sites

2c. Recruit subjects from Tampa VA & inpatient rehabilitation clinics (at NRN clinical sites)

- UNDERWAY OR PENDING HUMAN SUBJECTS APPROVAL

2d. Collect Phase evaluation data at initial and discharge

- UNDERWAY OR PENDING HUMAN SUBJECTS APPROVAL

2e. Data extractions requested from database, quality checks conducted.

- PENDING

Milestone #4. Produce Interim Report: Recruitment and Enrollment

- COMPLETE

Key Research Accomplishments

Human Subjects Approval

- University of Florida as the administrative, coordinating center for the study has IRB approval for the study.
- IRB approval is a three step process for each of the 7 NRN centers – 1) review and approval by the local institution, 2) review and approval by HRPO, and 3) review/revision by the parent institution, University of Florida to incorporate the additional site into the UF IRB protocol. We estimated that this process would take ~6 months but it has taken much longer because of the 3-step process and necessary revisions.
- Currently, University of Florida and Ohio State University have full approval and OSU has initiated patient recruitment. Three other centers have obtained institutional approval and are under review by HRPO. Two/three sites have received HRPO feedback and are now preparing minor revisions to their IRB as requested. Once revisions are approved at the local site IRB, these will then be resubmitted to HRPO, and when approved, submitted as a revision to the UF IRB for approval. We anticipate that this should be within the next month. One center

has IRB materials under review at their local institution after a local request for revision. Two centers have not submitted IRB materials for review at this time.
- The IRB proposal has been prepared for submission by the Tampa VA site. The Data Transfer Agreement has required several reviews by the University of Florida and Systemax Corporation in order to meet all of the necessary requirements of the involved parties. A final revision is in route to the Tampa VA for review.
- We estimate that we will complete in-patient and out-patient recruitment by 20 months. This estimate is in agreement with our statement of work but is contingent on the majority of centers and the Tampa VA receiving full approval within the next 4 weeks.

Consequences of Longer Time Period for Human Subject Approval

- Subject recruitment may take longer than the estimated 20 months if human subject approval continues to take longer than expected and if 2 centers do not pursue approval.
- *Solution*: Six/eight sites can increase enrollment at their facilities for the in-patient population of this study. This is a reasonable request as enrollment was targeted at 1 participant per month over a 10-12 month period in order to reach 9-11 enrollees per site. The in-patient population across the six sites is enough to meet this enrollment with a shift in resources to other sites to achieve the study enrollment within the allotted time. The sites are amenable to this strategy if necessary.
- *Solution*: Alternatively, a no cost extension may be needed to at the end of year 2 to allow sufficient time to complete recruitment, data analysis and manuscript preparation.

Training for NRS and Preparation for Data Collection

- All physical therapists from NRN centers were trained in use of the newest version of the NRS and underwent standardization training April 2011 at the NRN National Summit in Louisville, KY.
- 3 Tampa VA physical therapists underwent NRS training at Ohio State University. They were also trained in data entry through the ITW system created by Systemax Corporation for the proposal.
- Systemax created electronic data collection sites for all NRN centers and the Tampa VA. Data collection and entry methods were created and have been tested by all centers so that recruitment can begin immediately once human subject approval occurs.

Reportable Outcomes

None at this time

Conclusion

We have been largely successful in completing the required tasks for year 1. One unexpected barrier that slowed subject recruitment has been the length of the approval process for human subjects. We expect the majority of centers to have final approval within 1 month and to have large gains in subject recruitment over the subsequent 3 months. We will focus on reportable outcomes in year 2 including activation of the web site, submission of 1-2 manuscripts and dissemination of findings at national meetings.

References

None

Appendices

None